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EXAMINER	
FERNANDEZ, KATHERINE L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,368	LEFERE ET AL.	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16;18-27* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

1. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

2. Claims 15 and 22 are objected to because of the following informalities:

Claim 15 recites the limitation "over the 20 to 36 hour administration period" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the 24-hour administration period" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 19-21 and 23-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Lauenstein et al. ("MR Colonography with Barium-based Fecal Tagging: Initial Clinical Experience", Published online before print February 21, 2002).

With regards to claim 19, Lauenstein et al. disclose a method of preparing an individual for a predetermined activity; wherein said predetermined activity requires the tagging of at least some colonic residue in the individual's digestive tract; said method comprising the steps of (i) administering one or more food items having sufficient

tagging agent incorporated therein so that consumption of the one or more food items by the individual causes the stool to become tagged (pg. 249, middle column, 2nd paragraph; pg. 252, middle column, 3rd paragraph, referring to administering barium already mixed into prepackaged meals).

With regards to claim 20, Lauenstein et al. disclose that one or more food items are administered over at least a 24-hour period before the predetermined activity (pg. 249, middle column, 2nd paragraph, referring to meals given 36 hours before MR colonography).

With regards to claim 21, Lauenstein et al. disclose that each of the one or more food items comprises at from about 0.01 g to about 150 g of tagging agent, which is equivalent to from about 10 mg to about 150,000 mg of tagging agent (pg. 249, middle column, 2nd paragraph, referring to 1 mg/mL barium sulfate administered in a dose of 200 mL (i.e. 200 mg of barium sulfate) with each of the 4 principal meals, which falls within the limitation of 10 mg to 150,000 mg of tagging agent).

With regards to claim 23, although Lauenstein et al. do not specifically disclose that the individual's total fluid intake during the 24 hour administration period is 1 to 3 liters, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, it is inherent that an individual should be taking in a total fluid intake of about 1 to 2 liters, which is within the limitation of 1 to 3 liters.

With regards to claim 24, Lauenstein et al. disclose that the predetermined activity is barium enema (pg. 249, left column, 3rd paragraph).

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-2 and 5 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaufman et al. (US Patent No. 6,331,116).

With regards to claim 1, Kaufman et al. disclose a method of preparing an individual for a predetermined activity, wherein said predetermined activity requires the tagging of at least some colonic residue in the individual's digestive tract, said system comprising: a) administering less than 7 doses of a tagging agent over a 20 to 36 hour administration period (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three 250 cc doses (i.e. less than 7 doses) of Barium Sulfate (i.e. tagging agent) suspension during the day (i.e. 24 hour administration period)); wherein each dose of tagging agent comprises greater than 2% w/v tagging agent (column 16, lines 43-49, referring to Barium Sulfate suspension of

2.1% w/v). Kaufman further disclose that fluid intake is preferably increased during the day, noting that cranberry juice is known to provide increased bowel fluids, but water could also be ingested (column 16, lines 49-54). Although Kaufman et al. do not specifically disclose that about 1 to 4 liters of total fluid are administered over the 20 to 36 hour administration period, it is well known that the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, by disclosing that fluid intake is increased during the day (i.e. during the administration period), Kaufman et al. disclose that more than 2 liters should be administered, which would fall within the limitation of administering 1 to 4 liters of total fluid over the administration period. Kaufman et al. further disclose that the patient is free from administration of laxatives or cathartic for at least 24 hours (column 16, lines 64-67).

However, even if Kaufman et al. do not disclose the particular volume of fluid that is administered over the 20 to 36 hour administration period, they do teach increasing fluid intake, as mentioned above. It would have been obvious to one of ordinary skill in the art to have included in the method of Kaufman et al. the step of administering 1 to 4 liters of total fluid over the administration period, since Kaufman et al. teaches increasing fluid intake and it has generally been held to be within the skill level of the art to perform routine experimentation to determine appropriate parameters for implementing an invention, in particular to determine the sufficient amount of fluid intake needed to provide increased bowel fluids.

With regards to claim 2, Kaufman et al. disclose the administration of tagging agent is less than 5 doses; the volume of each dose ranging between 25 to 250 ml

(column 16, lines 43-49, referring to ingesting three 250 cc doses of Barium Sulfate); and wherein the total fluid intake is 1 to 3 liters over the 20 to 36 hour administration period (see above).

With regards to claim 5, Kaufman et al. disclose that the tagging agent is Barium Sulfate (column 16, lines 43-49).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. as applied to claims 1-2 above, and further in view of Johnson et al. (US Patent No. 6,477,401) and Illig et al. (US Patent No. 5,352,434).

With regards to claim 3, as discussed above, Kaufman et al. meet the limitations of claim 1. As discussed above, Kaufman discloses administering 3 doses with a volume from about 200 ml to 250 ml and comprises greater than 2% tagging agent (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three 250 cc doses (i.e. less than 7 doses) of Barium Sulfate (i.e. tagging agent) suspension of 2.1% w/v during the day (i.e. 24 hour administration period)). However, Kaufman et al. do not disclose that the administration of tagging agent is 4 doses; wherein the volume of one dose comprises at least 30% w/v tagging agent.

Johnson et al. disclose a method for generating colonography images for colorectal cancer screening (column 1, lines 64-66). Their method includes a step of administering a stool marker to the patient followed by imaging of the patient's colon (column 4, lines 13-17). They disclose that the period of administration ranged from 24 to 48 hours prior to imaging while the total number of doses administered ranged from 2 to 7 (column 9, lines 32-42). As can be seen from the chart in Figure 12, one group of individuals received 4 doses. Further, Johnson et al. teaches that the quality of the stool marking improves with a greater quantity of the stool marker administered to the patient (column 10, lines 32-39). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. to administer 4 doses of the tagging agent to the individual, as taught by Johnson et al., since between 2 and 7 doses are suitable for administering the tagging agent and the quality of the stool marking improves with a greater quantity of the stool marker administered to the patient (column 10, lines 32-39). However, Kaufman et al. in view of Johnson et al. do not disclose that the volume of one dose comprises at least 30% w/v tagging agent.

Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt (column 3, lines 13-27). They further disclose that the dosages of the contrast agent will vary according to the nature of

ingredients used, but should be kept as low as consistent with achieving contrast enhanced imaging (column 9, lines 28-34). They further disclose that the most preferred concentration is from about 15% w/v to about 40% w/v (the limitation of at least 30% w/v tagging agent falls in this range) (column 9, lines 48-52). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. in view of Johnson et al. to have the volume of one dose comprise of at least 30% w/v tagging agent, as taught by Illig et al., since a 30% concentration of the contrast agent falls within the preferrred range of 15% to about 40% w/v, and therefore a 30% concentration would be expected to provide efficient and effective contrast/tagging, as taught by Illig et al. (column 9, lines 28-46).

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. as applied to claim 1-2 above, and further in view of Illig et al.

With regards to claim 4, Kaufman et al. disclose the administration of tagging agent is 3 doses (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three doses of Barium Sulfate suspension). However, they do not disclose that the volume of each dose is about 20 ml and comprises about 40% w/v tagging agent. Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt. They further disclose that the dosages of the contrast agent will vary according to the nature of ingredients

used, but should be kept as low as consistent with achieving contrast enhanced imaging (3 doses of a volume of 20 mL can be considered low) (column 9, lines 28-47). They also disclose that the most preferred concentration is from about 15% w/w to about 40% w/w. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kaufman et al. to have the volume of each dose be about 20 mL and comprises about 40% w/v tagging agent, as taught by Illig et al, since it would have been obvious to try a low dosage (such as 20 mL) in order to reduce the toxicity potential, and a 40% concentration of the contrast agent falls within the preferrred range of 15% to about 40% w/v, and therefore a 40% concentration would be expected to provide efficient and effective contrast/tagging (column 9, lines 28-46).

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. as applied to claims 1-2 and 5 above, and further in view of Shah et al. (US Patent No. 6,039,975).

As discussed above, Kaufman et al. meet the limitations of claim 1. However, they do not specifically disclose that the tagging agent is combined with Sorbital or Mannitol. Shah et al. disclose an oral delivery system for delivering a precise amount of a pharmaceutical product to the colon without premature delivery of the product to the upper gastrointestinal (GI) tract (column 1, lines 7-12). They disclose that their drug delivery system is a tablet comprising of three parts: 1) an outer enteric coating; 2) an inner semi-permeable polymer membrane containing a plasticizer; and 3) a central core comprising a swelling agent and an active ingredient; the three parts function to provide release of drug to the colon without premature delivery of the drug to the upper GI tract

(column 2, lines 59-66). They further disclose that a preferred swelling agent is Mannitol (column 4, lines 6-17). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Kaufman et al. to have the tagging agent combined with Mannitol, as taught by Shah et al., as Mannitol can be used as a swelling agent and can be used to ensure that the tagging agent is delivered to the colon without premature delivery of the tagging agent to the upper gastrointestinal tract (column 4, lines 6-17; column 1, lines 7-12).

12. Claims 7-9, 11-12, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining et al. (US Patent No. 5,782,762) in view of The Children's Hopsital at Westmead Fact Sheet: Low Residue Diet, from now on referred to as CHW (Internet, August 2000, http://web.archive.org/web/20010713061634/http://www.chw.edu.au/parents/factsheets/folowres.htm), and further in view of Shah et al.

With regards to claims 7-9, 11, and 25, Vining et al. disclose a method and system for generating and displaying interactive, three-dimensional structures, such as the colon (column 5, lines 24-34). The method for imaging the colon includes the initial step of cleansing the colon (column 8, lines 1-4). As an alternative to cleansing the colon, the patient can be fed a low residue diet combined with a contrast agent (i.e. a tagging marker of the colonic residue), such as Barium Sulfate, for about 3 days (column 8, lines 12-20).

However, they do not specifically disclose that this low-residue diet would consist of food items that meet the limitations of claims 7-9 (i.e. comprising 100 calories, at

least 0.5 grams of dietary fiber, at least 0.5% of the calories derived from fat, at least 1% by weight of solid material, more than 600 calories, less than about 15 grams of dietary fiber, etc). They also do not specifically disclose that one or more food components are selected from the group consisting of nutritional drinks, beverages, soup products, starch foods, grain foods, protein supplements, fruit foods and vegetable foods. Further, they do not disclose that one or more food items constitute a first feeding, a second feeding, and a third feeding. Also, they do not disclose that the tagging agent is combined with Sorbitol or Mannitol.

CHW disclose a low residue diet to reduce both the number and size of stools (pg.1, lines 8-9). They disclose that foods that are allowed each day for the diet which include foods such as white pasta, white rice, meat, avocado, butter, and pumpkin (Table: Foods allowed each day). The listed allowed foods fall into the groups listed in the instant claim 11. Further, the diet should have 7-10 g of dietary fiber per day (pg.1, line 7). Selection from the foods listed would meet the limitations of claims 7-9 and 11 (i.e. comprising at least 100 calories, at least 0.5 % of calories are derived from fat, from about 600 to about 2000 calories, etc.). With regards to claim 25, CHW disclose a typical daily intake, which consists of breakfast, lunch, and dinner (i.e. first feeding, second feeding, third feeding) (pg. 2). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. to have the low residue diet meet the limitations of instant claims 7-9 and 11, as taught by CHW, since doing so would reduce both the number and size of stools, as taught by

CHW (pg 1. lines 8-9). However, Vining et al. in view of CHW do not disclose that the tagging agent is combined with Sorbitol or Mannitol.

Shah et al. disclose an oral delivery system for delivering a precise amount of a pharmaceutical product to the colon without premature delivery of the product to the upper gastrointestinal (GI) tract (column 1, lines 7-12). They disclose that their drug delivery system is a tablet comprising of three parts: 1) an outer enteric coating; 2) an inner semi-permeable polymer membrane containing a plasticizer; and 3) a central core comprising a swelling agent and an active ingredient; the three parts function to provide release of drug to the colon without premature delivery of the drug to the upper GI tract (column 2, lines 59-66). They further disclose that a preferred swelling agent is Mannitol (column 4, lines 6-17). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the method of Vining et al. in view of CHW to have the tagging agent combined with Mannitol, as taught by Shah et al., as Mannitol can be used as a swelling agent and can be used to ensure that the tagging agent is delivered to the colon without premature delivery of the tagging agent to the upper gastrointestinal tract (column 4, lines 6-17; column 1, lines 7-12).

With regards to claim 12, as discussed above, Vining et al. in view of CHW and Shah meet the limitations of claim 7. Although they do not specifically disclose that the total fluid intake by the individual is about 1-2 liters, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, an individual should be taking in a total fluid intake of about 1 to 2 liters.

13. Claims 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. ("MR Colonography Without Colonic Cleansing: A New Strategy to Improve Patient Acceptance", October 2001) in view of Callstrom et al. ("CT Colonography without Cathartic Preparation: Feasibility Study", June 2001).

With regards to claim 13, Lauenstein et al. disclose a method for generating radiography images of one or more sections of an individual's gastrointestinal tract for screening, comprising (i) administering to the individual a low residue diet over a 36 hour period (pg. 824, left column, 2nd paragraph, referring to four principal low-fiber meals); (ii) administering to the individual one or more doses of a tagging agent over the 36 hour period (pg.824, left column, 2nd paragraph, referring to 200 mL of a barium sulfate containing contrast agent); (iii) with the patient free from administration of laxatives or cathartics for at least 24 hours, imaging one or more sections of the individual's gastrointestinal tract after the administration period (pg. 823, OBJECTIVE, referring to development of a strategy obviating colonic cleansing by performing MR colonography in conjunction with fecal tagging; pg. 824, Subjects and Methods); (iv) producing a radiography image of the one or more sections of the individual's gastrointestinal tract; said image showing stool marked with the tagging agent (see Figure 2, MR image of an individual after fecal tagging, stool is marked with the tagging agent); (v) screening the radiography image to identify the presence of any abnormality in the gastrointestinal tract without removing and/or subtracting the marked stool from the images (See Figures 2 and 3; pg. 826, right column, 2nd paragraph, referring to identifying colonic carcinomas and polyps, also the marked stool is not removed and/or

subtracted from the images). However, Lauenstein et al. do not disclose that the administration period is at least a 48-hour period.

Callstrom et al. disclose a study evaluating the methods for contrast material labeling of stool in the unprepared colon for computed tomography (CT) colonography and to determine their sensitivity for polyp detection (pg. 693, PURPOSE); They disclose that two to seven doses of 225 mL of dilute contrast material were orally administered during 24 or 48 hours and transverse CT images were assessed for effectiveness of stool labeling (pg. 693, MATERIALS AND METHODS). They concluded that a 48 hour administration period for ingestion of the contrast material is optimal (pg. 698, left column, 2nd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to have the administration period be at least a 48-hour period, as taught by Callstrom et al, as they have found 48 hours to be an optimal administration period for ingestion of the contrast material (pg. 698, left column, 2nd paragraph).

With regards to claim 14, as discussed above, Lauenstein et al. in view of Callstrom et al. meet the limitations of claim 13. Further, Lauenstein et al. disclose that the images are produced in connection with a predetermined activity, including MR colonography of the individual's colon (pg. 823, OBJECTIVE).

With regards to claim 15, as discussed above, Lauenstein et al. in view of Callstrom et al. meet the limitations of claim 13. Further Lauenstein et al. disclose that the administration of tagging agent is less than 5 doses and the volume of each does ranging between 25 to 250 mL (pg. 824, left column, 2nd paragraph, referring to 200 mL

of barium sulfate containing contrast agent was ingested with each of 4 principal low-fiber meals (i.e. 4 doses). Although they do not specifically disclose that the total fluid intake is 1 to 3 liters over a 20 to 36 hour administration period, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, it is inherent that an individual should be taking in a total fluid intake of about 1 to 2 liters, which is within the limitation of 1 to 3 liters.

With regards to claim 18, as discussed above, Lauenstein et al. in view of Callstrom et al. meet the limitations of claim 13. Further, Lauenstein et al. disclose that the tagging agent is Barium Sulfate (pg. 824, left column, 2nd paragraph).

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. in view of Callstrom et al. as applied to claims 13-15 above, and further in view of Illig et al. (US Patent No. 5,352,434).

With regards to claim 16, as discussed above, Lauenstein et al. in view of Callstrom et al. meet the limitations of claim 13. Further, Lauenstein et al. disclose that the administration of tagging agent is 4 doses, and further that the volume of the doses is 200 mL. However, they do not specifically disclose that the volume of one dose comprises at least 30% w/v tagging agent and the volume of the remaining 3 doses comprises greater than 2% w/v tagging agent. Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt

(column 3, lines 13-28). They further disclose that the most preferred concentration is from about 15% w/w to about 40% w/w (column 9, lines 48-52). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. in view of Callstrom et al. to have the volume of one dose comprise at least 30% w/v tagging agent and the volume of the remaining 3 doses comprise greater than 2% w/v tagging agent, as taught by Illig et al., since a 30% or greater than 2% concentration of the contrast agent falls within the preferrred range of 15% to about 40% w/v, and therefore a 30% or greater than 2% concentration would be expected to provide efficient and effective contrast/tagging (column 9, lines 28-46).

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. in view of Callstrom et al. as applied to claim 13 above, and further in view Kaufman et al. and Illig et al.

With regards to claim 17, as discussed above, the combined references of Lauenstein et al. and Callstrom meet the limitations of claim 13. Further, Lauenstein et al. disclose that the administration of tagging agent in one or more doses. However, they do not specifically disclose the administration of tagging agent is 3 doses, wherein the volume of each dose is about 20 ml and comprises about 40% w/v tagging agent.

Kaufman et al. disclose the administration of tagging agent is 3 doses (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three doses of Barium Sulfate suspension). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. in view of Callstrom et al. to have the administration of tagging agent in

3 doses, as taught by Kaufman et al., since 3 doses has been previously shown to be successful in tagging stool and therefore it would have been obvious to try 3 doses (column 16, lines 43-49). However, Lauenstein et al. in view of Callstrom et al. and Kaufman et al. do not specifically disclose that the volume of each dose is about 20 mL and comprises about 40% w/v tagging agent.

Illig et al. disclose compositions for coating the gastrointestinal tract of mammals to form an effective radiopaque coating thereon by which diagnostic examination of the GI tract may be accomplished (column 2, lines 50-54). They disclose that Barium Sulfate is the preferred x-ray contrast agent, and the compositions contain from about 5% w/w to about 95% w/w of the barium salt. They further disclose that the dosages of the contrast agent will vary according to the nature of ingredients used, but should be kept as low as consistent with achieving contrast enhanced imaging (3 doses of a volume of 20 mL can be considered low) (column 9, lines 28-47). They also disclose that the most preferred concentration is from about 15% w/w to about 40% w/w. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. in view of Callstrom et al. and Kaufman et al. to have the volume of each dose be about 20 mL and comprises about 40% w/v tagging agent, as taught by Illig et al, since it would have been obvious to try a low dosage, such as 20 mL, in order to reduce the toxicity potential, and a 40% concentration of the contrast agent falls within the preferrred range of 15% to about 40% w/v, and therefore a 40% concentration would be expected to provide efficient and effective contrast/tagging (column 9, lines 28-46).

16. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al.

With regards to claim 22, although Lauenstein et al. do not specifically disclose that the total amount of tagging agent consumed by the individual during the at least 24 hour administration period is at least 1g, Lauenstein et al. do disclose that 0.8 g. of the tagging agent is consumed during the at least 24 hour administration period (pg. 249, middle column, 2nd paragraph, referring to 1 mg/mL barium sulfate administered in a dose of 200 mL (i.e. 200 mg of barium sulfate) with each of the 4 principal meals, which is 0.8 g consumed during the at least 24 hour administration period). It would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to have the total amount of tagging agent consumed by the individual during the at least 24 hour administration period be at least 1g, as it has generally been held to be within the skill level of the art to perform routine experimentation to determine appropriate parameters for implementing an invention, in particular to determine the sufficient dosage to tag stool.

17. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. as applied to claim 19 above, and further in view of Li et al. ("An image segmentation approach to extract colon lumen through colonic material tagging and hidden Markov random field model for virtual colonoscopy", February 2002) as cited by applicant.

As discussed above, Lauenstein et al. meet the limitations of claim 19. However, they do not specifically disclose that their method further comprises the step of

providing a mild laxative regimen prior to the predetermined activity. Li et al. disclose an electronic colon cleansing technology, which employs a hidden Markov random field model to integrate the neighborhood information for overcoming the non-uniformity problems within the tagged stool/fluid region (see Abstract). They disclose that their method includes having the patient undergo a one-day bowel preparation of mild laxatives and a low residue diet, which is less unpleasant to a patient than a physical colon washing, such as Golytly (2nd page, first paragraph, and 2nd page, Section 2.1). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to further comprise the step of providing a mild laxative regimen prior to the predetermined activity, as taught by Li et al, as an alternative approach to cleansing the bowel that is less unpleasant to patients (2nd page, first paragraph).

18. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. as applied to claim 19 above, and further in view of Callstrom et al.

As discussed above, Lauenstein et al. meet the limitations of claim 19. However, they do not specifically disclose that the last dose is administered to the individual more than 8 hours prior to the predetermined activity. Callstrom et al. disclose a study evaluating the methods for contrast material labeling of stool in the unprepared colon for computed tomography (CT) colonography and to determine their sensitivity for polyp detection (pg. 693, PURPOSE); They disclose that two to seven doses of 225 mL of dilute contrast material were orally administered during 24 or 48 hours and transverse CT images were assessed for effectiveness of stool labeling (pg. 693, MATERIALS

AND METHODS). They disclose that for a 48 hour, 4 dose group, with the last dose administered 12 hours prior to the CT colonography (pg. 694, middle column, 2nd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to have the last dose administered to the individual more than 8 hours prior to the predetermined activity, as taught by Callstrom et al., as this has been shown to provide the best specificity (see pg. 696, Table: Results of Contrast Material Labeling of Stool at CT Colonography)/

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERIC F. WINAKUR
PRIMARY EXAMINER